

CHARLES F. PREUSS (State Bar No. 45783)
BRENDA N. BUONAIUTO (State Bar No. 173919)
DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
50 Fremont Street, 20th Floor
San Francisco, California 94105
Telephone: (415) 591-7500
Facsimile: (415) 591-7510

FILED

JUN 29 2007

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Attorneys for Defendants
ORTHO-MCNEIL PHARMACEUTICAL, INC.
and MCKESSON CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

EDL

SAN FRANCISCO DIVISION

ARGENBRIGHT, JENIFER, an individual;
BROWN, BERLINE, an individual;
BURGOS, JENNIFER, an individual;
CLAY, AMANDA, an individual;
COOPER, TAMEKIA, an individual;
DORSEY, KIYANA, an individual;
DOWDY, VALENCIA, an individual;
EMBURY, PATRICIA, an individual;
EVANS, TENILLE, an individual;
GREENWALT, MARTHA, an individual;
HEBERT, BRANDY, an individual;
HENDERSON, YOLANDA, an individual;
HENNING, RAINA, an individual;
HERNANDEZ, AMY, an individual;
HODGES, CARRISA, an individual;
JASON, ALIKE, an individual;
JENNINGS, CHRISTIE, an individual;
JOHNSON, KAYLA, an individual;
KLAHS, REBECCA, an individual;
LAMPKA, NANCY, an individual;
LEAVY, TASHA, an individual;
LUCAS, PAMELA, an individual;
MARTIN, KATIE, an individual; MASON,
SHARON, an individual; MAUPIN,
CALLENA, an individual; MCMILLIAN,
MICHELLE, an individual; MEDJESKY,
DAYANITA, an individual; MEYER,

Case No. 07

3423

**DEFENDANTS' ANSWER TO
PLAINTIFFS' COMPLAINT; DEMAND
FOR JURY TRIAL**

CRYSTAL, an individual; MEZA, TONI, an individual; MILLER, STEPHANY, an individual; MOCZULSKI, KATHERINE, an individual; MORGAN, BETHANY, an individual; PADILLA, ANA, an individual; PEREZ, BRENDA B., an individual; PLUMMER, DIANA, an individual; PREVOST, LATOSHA, an individual; ROBLES, JULIE, an individual; SANDOVAL, SYLVIA, an individual; SHEARD, SHANELL, an individual; SIMS, SHERI, an individual; SMITH, HELEN, an individual; SPANN, JORETH, an individual; SPENCER, KAMIKA, an individual; SPURRIER, HEATHER, an individual; STAHL, REBECCA, an individual; TANIS, KATIE, an individual; THOMAS, ANTONIA, an individual; VALEAD, BRITNEY, an individual; VALENTIN, ERICA, an individual; WALSH-MONTANEZ, KRISTIN, an individual; WILLIAMS, EMILIA, an individual; WORKMAN, REBECCA, an individual; ZALES, MELISSA, an individual,

Plaintiffs,

v.

ORTHO-MCNEIL PHARMACEUTICAL, INC., a Delaware Corporation; MCKESSON CORP. and DOES 1-500, inclusive,

Defendants.

Defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP") and McKesson Corporation ("McKesson") (collectively "Defendants") by and through counsel, hereby respond to the allegations set forth in Plaintiffs' Complaint as follows:

ANSWER TO INTRODUCTION

1. Defendants are without knowledge or information sufficient to form a

1 belief as to Plaintiffs' allegations that they used ORTHO EVRA®. Defendants deny the
2 remaining allegations contained in paragraph 1 of Plaintiffs' Complaint.

3 2. Defendants admit that defendant OMP manufactured, advertised, promoted,
4 marketed, sold and distributed ORTHO EVRA®. Defendants deny the remaining
5 allegations contained in paragraph 2 of Plaintiffs' Complaint.

6 3. Defendants admit that defendant McKesson is a non-exclusive distributor
7 of ORTHO EVRA® and has its principal place of business in San Francisco, California.
8 Defendants deny the remaining allegations contained in paragraph 3 of Plaintiffs'
9 Complaint.

10 4. Defendants admit that on the ORTHO EVRA® Web site, it states that:
11 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents
12 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl
13 estradiol (progestin and estrogen, respectively) through the skin and into the
14 bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for
15 the prevention of pregnancy in November 2001. Defendants further admit that the FDA's
16 publications state what they state. Defendants deny the remaining allegations contained
17 in paragraph 4 of Plaintiffs' Complaint.

18 ANSWER TO JURISDICTION AND VENUE

19 5. Paragraph 5 of Plaintiffs' Complaint contains legal conclusions to which no
20 response is required.

21 6. Defendants admit that OMP is a Delaware corporation with its principal
22 place of business in New Jersey, and McKesson is a Delaware corporation with its
23 principal place of business in California. Defendants deny the remaining allegations
24 contained in paragraph 6 of Plaintiffs' Complaint.

25 7. Defendants admit that McKesson has its principal place of business in San
26 Francisco, California. Defendants deny the remaining allegations contained in paragraph
27 7 of Plaintiffs' Complaint.

28 8. Defendants admit that McKesson has its principal place of business in San

1 Francisco, California. Defendants deny the remaining allegations contained in paragraph
2 8 of Plaintiffs' Complaint.

3 9. Defendants are without knowledge or information sufficient to form a
4 belief as to the allegations contained in paragraph 9 of Plaintiffs' Complaint.

5 **ANSWER TO PLAINTIFFS**

6 10. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 10
9 of Plaintiffs' Complaint.

10 11. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 11
13 of Plaintiffs' Complaint.

14 12. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 12
17 of Plaintiffs' Complaint.

18 13. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 13
21 of Plaintiffs' Complaint.

22 14. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 14
25 of Plaintiffs' Complaint.

26 15. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 15

1 of Plaintiffs' Complaint.

2 16. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 16
5 of Plaintiffs' Complaint.

6 17. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 17
9 of Plaintiffs' Complaint.

10 18. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 18
13 of Plaintiffs' Complaint.

14 19. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 19
17 of Plaintiffs' Complaint.

18 20. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 20
21 of Plaintiffs' Complaint.

22 21. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 21
25 of Plaintiffs' Complaint.

26 22. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 22

1 of Plaintiffs' Complaint.

2 23. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 23
5 of Plaintiffs' Complaint.

6 24. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 24
9 of Plaintiffs' Complaint.

10 25. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 25
13 of Plaintiffs' Complaint.

14 26. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 26
17 of Plaintiffs' Complaint.

18 27. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 27
21 of Plaintiffs' Complaint.

22 28. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 28
25 of Plaintiffs' Complaint.

26 29. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 29

1 of Plaintiffs' Complaint.

2 30. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 30
5 of Plaintiffs' Complaint.

6 31. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 31
9 of Plaintiffs' Complaint.

10 32. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 32
13 of Plaintiffs' Complaint.

14 33. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 33
17 of Plaintiffs' Complaint.

18 34. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 34
21 of Plaintiffs' Complaint.

22 35. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 35
25 of Plaintiffs' Complaint.

26 36. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 36

1 of Plaintiffs' Complaint.

2 37. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 37
5 of Plaintiffs' Complaint.

6 38. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 38
9 of Plaintiffs' Complaint.

10 39. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 39
13 of Plaintiffs' Complaint.

14 40. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 40
17 of Plaintiffs' Complaint.

18 41. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 41
21 of Plaintiffs' Complaint.

22 42. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 42
25 of Plaintiffs' Complaint.

26 43. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 43

1 of Plaintiffs' Complaint.

2 44. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 44
5 of Plaintiffs' Complaint.

6 45. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 45
9 of Plaintiffs' Complaint.

10 46. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 46
13 of Plaintiffs' Complaint.

14 47. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 47
17 of Plaintiffs' Complaint.

18 48. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 48
21 of Plaintiffs' Complaint.

22 49. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 49
25 of Plaintiffs' Complaint.

26 50. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 50

1 of Plaintiffs' Complaint.

2 51. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 51
5 of Plaintiffs' Complaint.

6 52. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 52
9 of Plaintiffs' Complaint.

10 53. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 53
13 of Plaintiffs' Complaint.

14 54. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 54
17 of Plaintiffs' Complaint.

18 55. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 55
21 of Plaintiffs' Complaint.

22 56. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 56
25 of Plaintiffs' Complaint.

26 57. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 57

1 of Plaintiffs' Complaint.

2 58. Defendants are without knowledge or information sufficient to form a
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 58
5 of Plaintiffs' Complaint.

6 59. Defendants are without knowledge or information sufficient to form a
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 59
9 of Plaintiffs' Complaint.

10 60. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 60
13 of Plaintiffs' Complaint.

14 61. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 61
17 of Plaintiffs' Complaint.

18 62. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 62
21 of Plaintiffs' Complaint.

22 **ANSWER TO DEFENDANTS**

23 63. Defendants admit that OMP is a Delaware corporation with its principal
24 place of business in New Jersey. Defendants deny the remaining allegations contained in
25 paragraph 63 of Plaintiffs' Complaint.

26 64. Defendants admit that OMP conducts business in California. Defendants
27 deny the remaining allegations contained in paragraph 64 of Plaintiffs' Complaint.

28 65. Defendants are without knowledge or information sufficient to form a

1 belief as to the allegations contained in paragraph 65 of Plaintiffs' Complaint, and
2 therefore these allegations are denied.

3 66. Defendants are without knowledge or information sufficient to form a
4 belief as to the allegations contained in paragraph 66 of Plaintiffs' Complaint, and
5 therefore these allegations are denied.

6 67. Defendants admit that OMP manufactured, marketed, promoted, sold and
7 distributed ORTHO EVRA®. Defendants deny the remaining allegations contained in
8 paragraph 67 of Plaintiffs' Complaint.

9 68. Defendants admit that McKesson is a Delaware corporation with its
10 principal place of business in San Francisco, California. Defendants further admit that
11 McKesson conducts business in California. Defendants deny the remaining allegations
12 contained in paragraph 68 of Plaintiffs' Complaint.

13 69. Defendants are without knowledge or information sufficient to form a
14 belief as to the allegations contained in paragraph 69 of Plaintiffs' Complaint, and
15 therefore these allegations are denied.

16 70. Defendants are without knowledge or information sufficient to form a
17 belief as to the allegations contained in paragraph 70 of Plaintiffs' Complaint, and
18 therefore these allegations are denied.

19 71. Defendants admit that McKesson is a non-exclusive distributor of ORTHO
20 EVRA®. Defendants deny the remaining allegations contained in paragraph 71 of
21 Plaintiffs' Complaint.

22 72. Defendants are without knowledge or information sufficient to form a
23 belief as to the allegations contained in paragraph 72 of Plaintiffs' Complaint.

24 73. Defendants are without knowledge or information sufficient to form a
25 belief as to the allegations contained in paragraph 73 of Plaintiffs' Complaint.

26 74. To the extent that paragraph 74 of Plaintiffs' Complaint alleges improper
27 conduct on the part of Defendants, such allegations are denied.

28 75. To the extent that paragraph 75 of Plaintiffs' Complaint alleges improper

1 conduct on the part of Defendants, such allegations are denied.

2 **ANSWER TO GENERAL ALLEGATIONS**

3 76. OMP admits that on the Ortho-McNeil Pharmaceutical, Inc. Web site, it
4 states that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in
5 women's health care. Ortho-McNeil offers the broadest range of prescription birth
6 control options..." OMP further admits that it manufactures and sells ORTHO EVRA®,
7 the first combination transdermal contraceptive patch. Defendants deny the remaining
8 allegations contained in paragraph 76 of Plaintiffs' Complaint.

9 77. OMP admits that ORTHO EVRA® is the first and only once-a-week birth
10 control patch. Defendant OMP further admits that on the ORTHO EVRA® Web site, it
11 states that: "The transdermal -- or 'through the skin' -- weekly birth control patch
12 prevents pregnancy by delivering continuous levels of the hormones norelgestromin and
13 ethinyl estradiol (progestin and estrogen, respectively) through the skin and into the
14 bloodstream." Defendants deny the remaining allegations contained in paragraph 77 of
15 Plaintiffs' Complaint.

16 78. Defendants admit that a New Drug Application ("NDA") was filed for
17 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants
18 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it
19 states. Defendants deny the remaining allegations contained in paragraph 78 of
20 Plaintiffs' Complaint.

21 79. Defendants admit that the FDA approved the use of ORTHO EVRA® for
22 the prevention of pregnancy in November 2001. Defendants deny the remaining
23 allegations contained in paragraph 79 of Plaintiffs' Complaint.

24 80. Defendants admit that as with all prescription medicine, adverse events are
25 reported to the FDA by a variety of people and entities. Defendants deny the remaining
26 allegations contained in paragraph 80 of Plaintiffs' Complaint.

27 81. Defendants admit that the FDA's publications state what they state.
28 Defendants deny the remaining allegations contained in paragraph 81 of Plaintiffs'

1 Complaint.

2 82. Defendants admit that the November 2005 package insert for ORTHO
3 EVRA® states what it states. To the extent that paragraph 82 of Plaintiffs' Complaint
4 alleges improper conduct on the part of Defendants, such allegations are denied.

5 83. OMP admits that ORTHO EVRA® is the first and only once-a-week birth
6 control patch. Defendants deny the remaining allegations contained in paragraph 83 of
7 Plaintiffs' Complaint.

8 84. Defendants deny the allegations contained in paragraph 84 of Plaintiffs'
9 Complaint.

10 85. Defendants admit that the package insert for ORTHO EVRA® states what
11 it states. To the extent that paragraph 85 of Plaintiffs' Complaint alleges improper
12 conduct on the part of Defendants, such allegations are denied.

13 86. Defendants deny the allegations contained in paragraph 86 of Plaintiffs'
14 Complaint.

15 87. Defendants state that they were subject only to those duties imposed by
16 applicable law, and deny the allegations contained in paragraph 87 of Plaintiffs'
17 Complaint to the extent they suggest any different or greater duties. Defendants further
18 deny that they failed to abide by any applicable legal duties.

19 88. Defendants deny the allegations contained in paragraph 88 of Plaintiffs'
20 Complaint.

21 89. Defendants deny the allegations contained in paragraph 89 of Plaintiffs'
22 Complaint.

23 90. Defendants deny the allegations contained in paragraph 90 of Plaintiffs'
24 Complaint.

25 91. Defendants deny the allegations contained in paragraph 91 of Plaintiffs'
26 Complaint.

27 **ANSWER TO FRAUDULENT CONCEALMENT**

28 92. Defendants deny the allegations contained in paragraph 92 of Plaintiffs'

1 Complaint.

2 93. Defendants state that they were subject only to those duties imposed by
3 applicable law, and deny the allegations contained in paragraph 93 of Plaintiffs'
4 Complaint to the extent they suggest any different or greater duties. Defendants further
5 deny that they failed to abide by any applicable legal duties, and deny the remaining
6 allegations contained in this paragraph.

7 **ANSWER TO FIRST CAUSE OF ACTION**
8 **NEGLIGENCE**

9 94. Defendants repeat their answers to the allegations of paragraphs 1 through
10 93 of Plaintiffs' Complaint as if set forth at length herein.

11 95. Defendants state that they were subject only to those duties imposed by
12 applicable law, and deny the allegations contained in paragraph 95 of the First Cause of
13 Action of Plaintiffs' Complaint to the extent they suggest any different or greater duties.
14 Defendants further deny that they failed to abide by any applicable legal duties.

15 96. Defendants deny the allegations contained in paragraph 96 of the First
16 Cause of Action of Plaintiffs' Complaint.

17 97. Defendants deny the allegations contained in paragraph 97 of the First
18 Cause of Action of Plaintiffs' Complaint.

19 98. Defendants deny the allegations contained in paragraph 98 of the First
20 Cause of Action of Plaintiffs' Complaint.

21 99. Defendants deny the allegations contained in paragraph 99 of the First
22 Cause of Action of Plaintiffs' Complaint.

23 100. Defendants deny the allegations contained in paragraph 100 of the First
24 Cause of Action of Plaintiffs' Complaint.

25 101. Defendants deny the allegations contained in paragraph 101 of the First
26 Cause of Action of Plaintiffs' Complaint.

27 102. Defendants deny the allegation that ORTHO EVRA® is defective, and
28 deny the remaining allegations contained in paragraph 102 of the First Cause of Action of

1 Plaintiffs' Complaint.

2 103. Defendants deny the allegations contained in paragraph 103 of the First
3 Cause of Action of Plaintiffs' Complaint.

4 104. Defendants deny the allegations contained in paragraph 104 of the First
5 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
6 the unnumbered paragraph following paragraph 104.

7 **ANSWER TO SECOND CAUSE OF ACTION**

8 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

9 105. Defendants repeat their answers to the allegations of paragraphs 1 through
10 104 of Plaintiffs' Complaint as if set forth at length herein.

11 106. Defendants admit that OMP manufactures and supplies ORTHO EVRA®.
12 Defendants deny the remaining allegations contained in paragraph 106 of the Second
13 Cause of Action of Plaintiffs' Complaint.

14 107. Defendants admit that OMP manufactures and supplies ORTHO EVRA®.
15 Defendants deny the remaining allegations contained in paragraph 107 of the Second
16 Cause of Action of Plaintiffs' Complaint.

17 108. Defendants deny the allegations contained in paragraph 108 of the Second
18 Cause of Action of Plaintiffs' Complaint.

19 109. Defendants deny the allegation that ORTHO EVRA® is defective, and
20 deny the remaining allegations contained in paragraph 109 of the Second Cause of Action
21 of Plaintiffs' Complaint.

22 110. Defendants deny the allegation that ORTHO EVRA® is defective, and
23 deny the remaining allegations contained in paragraph 110 of the Second Cause of Action
24 of Plaintiffs' Complaint.

25 111. Defendants deny the allegations contained in paragraph 111 of the Second
26 Cause of Action of Plaintiffs' Complaint.

27 112. Defendants deny the allegation that ORTHO EVRA® is defective, and
28 deny the remaining allegations contained in paragraph 112 of the Second Cause of Action

1 of Plaintiffs' Complaint.

2 113. Defendants deny the allegations contained in paragraph 113 of the Second
3 Cause of Action of Plaintiffs' Complaint.

4 114. Defendants deny the allegations contained in paragraph 114 of the Second
5 Cause of Action of Plaintiffs' Complaint.

6 115. Defendants deny the allegations contained in paragraph 115 of the Second
7 Cause of Action of Plaintiffs' Complaint.

8 116. Defendants deny the allegations contained in paragraph 116 of the Second
9 Cause of Action of Plaintiffs' Complaint.

10 117. Defendants deny the allegations contained in paragraph 117 of the Second
11 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
12 the unnumbered paragraph following paragraph 117.

13 **ANSWER TO THIRD CAUSE OF ACTION**

14 **BREACH OF EXPRESS WARRANTY**

15 118. Defendants repeat their answers to the allegations of paragraphs 1 through
16 117 of Plaintiffs' Complaint as if set forth at length herein.

17 119. Defendants deny the allegations contained in paragraph 119 of the Third
18 Cause of Action of Plaintiffs' Complaint.

19 120. Defendants deny the allegations contained in paragraph 120 of the Third
20 Cause of Action of Plaintiffs' Complaint.

21 121. Defendants deny the allegations contained in paragraph 121 of the Third
22 Cause of Action of Plaintiffs' Complaint.

23 122. Defendants deny the allegations contained in paragraph 122 of the Third
24 Cause of Action of Plaintiffs' Complaint.

25 123. Defendants deny the allegations contained in paragraph 123 of the Third
26 Cause of Action of Plaintiffs' Complaint.

27 124. Defendants deny the allegations contained in paragraph 124 of the Third
28 Cause of Action of Plaintiffs' Complaint.

125. Defendants deny the allegations contained in paragraph 125 of the Third Cause of Action of Plaintiffs' Complaint.

126. Defendants deny the allegations contained in paragraph 126 of the Third Cause of Action of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in paragraph 127 of the Third Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 127.

ANSWER TO FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

128. Defendants repeat their answers to the allegations of paragraphs 1 through 127 of Plaintiffs' Complaint as if set forth at length herein.

129. Defendants admit that OMP marketed, sold and distributed ORTHO EVRA®, which is used for the prevention of pregnancy. Defendants further admit that McKesson is a non-exclusive distributor of ORTHO EVRA®, and deny that McKesson marketed or sold ORTHO EVRA®. The remainder of paragraph 129 of the Fourth Cause of Action of Plaintiffs' Complaint contains a legal conclusion to which no response is required.

130. Paragraph 130 of the Fourth Cause of Action of Plaintiffs' Complaint contains legal conclusions to which no response is required.

131. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 131 of the Fourth Cause of Action of Plaintiffs' Complaint, and therefore these allegations are denied.

132. Defendants deny the allegations contained in paragraph 132 of the Fourth Cause of Action of Plaintiffs' Complaint.

133. Defendants deny the allegations contained in paragraph 133 of the Fourth Cause of Action of Plaintiffs' Complaint.

134. Defendants deny the allegations contained in paragraph 134 of the Fourth Cause of Action of Plaintiffs' Complaint.

1 135. Defendants deny the allegations contained in paragraph 135 of the Fourth
2 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
3 the unnumbered paragraph following paragraph 135.

4 **ANSWER TO FIFTH CAUSE OF ACTION**
5 **NEGLIGENT MISREPRESENTATION**

6 136. Defendants repeat their answers to the allegations of paragraphs 1 through
7 135 of Plaintiffs' Complaint as if set forth at length herein.

8 137. Defendants admit that OMP manufactures, markets, promotes, and sells
9 ORTHO EVRA®. Defendants further state that they were subject only to those duties
10 imposed by applicable law, and deny the allegations contained in this paragraph to the
11 extent they suggest any different or greater duties. Defendants further deny that they
12 failed to abide by any applicable legal duties, and deny the remaining allegations
13 contained in paragraph 137 of the Fifth Cause of Action of Plaintiffs' Complaint.

14 138. Defendants deny the allegations contained in paragraph 138 of the Fifth
15 Cause of Action of Plaintiffs' Complaint.

16 139. Defendants deny the allegations contained in paragraph 139 of the Fifth
17 Cause of Action of Plaintiffs' Complaint.

18 140. Defendants deny the allegations contained in paragraph 140 of the Fifth
19 Cause of Action of Plaintiffs' Complaint.

20 141. Defendants deny the allegations contained in paragraph 141 of the Fifth
21 Cause of Action of Plaintiffs' Complaint.

22 142. Defendants deny the allegations contained in paragraph 142 of the Fifth
23 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
24 the unnumbered paragraph following paragraph 142.

25 **ANSWER TO SIXTH CAUSE OF ACTION**

26 **FRAUD**

27 143. Defendants repeat their answers to the allegations of paragraphs 1 through
28 142 of Plaintiffs' Complaint as if set forth at length herein.

1 144. Defendants admit that OMP manufactures, markets, promotes, and sells
2 ORTHO EVRA®. Defendants further state that they were subject only to those duties
3 imposed by applicable law, and deny the allegations contained in this paragraph to the
4 extent they suggest any different or greater duties. Defendants further deny that they
5 failed to abide by any applicable legal duties, and deny the remaining allegations
6 contained in paragraph 144 of the Sixth Cause of Action of Plaintiffs' Complaint.

7 145. Defendants deny the allegations contained in paragraph 145 of the Sixth
8 Cause of Action of Plaintiffs' Complaint.

9 146. Defendants deny the allegations contained in paragraph 146 of the Sixth
10 Cause of Action of Plaintiffs' Complaint.

11 147. Defendants deny the allegations contained in paragraph 147 of the Sixth
12 Cause of Action of Plaintiffs' Complaint.

13 148. Defendants deny the allegations contained in paragraph 148 of the Sixth
14 Cause of Action of Plaintiffs' Complaint.

15 149. Defendants deny the allegations contained in paragraph 149 of the Sixth
16 Cause of Action of Plaintiffs' Complaint.

17 150. Defendants deny the allegations contained in paragraph 150 of the Sixth
18 Cause of Action of Plaintiffs' Complaint.

19 151. Defendants deny the allegations contained in paragraph 151 of the Sixth
20 Cause of Action of Plaintiffs' Complaint.

21 152. Defendants are without knowledge or information sufficient to form a
22 belief as to Plaintiffs' states of mind. Defendants deny the remaining allegations
23 contained in paragraph 152 of the Sixth Cause of Action of Plaintiffs' Complaint.

24 153. Defendants deny the allegations contained in paragraph 153 of the Sixth
25 Cause of Action of Plaintiffs' Complaint.

26 154. Defendants deny the allegations contained in paragraph 154 of the Sixth
27 Cause of Action of Plaintiffs' Complaint.

28 155. Defendants deny the allegations contained in paragraph 155 of the Sixth

1 Cause of Action of Plaintiffs' Complaint.

2 156. Defendants deny the allegations contained in paragraph 156 of the Sixth
3 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
4 the unnumbered paragraph following paragraph 156.

5 **FIRST AFFIRMATIVE DEFENSE**

6 Plaintiffs' Complaint fails to state a claim against Defendants upon which relief
7 may be granted.

8 **SECOND AFFIRMATIVE DEFENSE**

9 Venue is improper in this court.

10 **THIRD AFFIRMATIVE DEFENSE**

11 Plaintiffs are fraudulently joined and/or misjoined, and the court should sever
12 Plaintiffs' claims and/or enter other appropriate orders to avoid prejudice, unfairness,
13 hardship, delay, and undue expense and to promote convenience and expedience.

14 **FOURTH AFFIRMATIVE DEFENSE**

15 Plaintiffs' claims are barred, in whole or in part, to the extent certain Plaintiffs
16 have asserted duplicative claims in one or more other actions pending against some or all
17 of the same defendants.

18 **FIFTH AFFIRMATIVE DEFENSE**

19 Plaintiffs' claims are barred by the applicable statute of limitations, statute of
20 repose and/or by the equitable doctrines of laches and estoppel.

21 **SIXTH AFFIRMATIVE DEFENSE**

22 Plaintiffs' claims are barred by the doctrines of informed consent, release and
23 waiver.

24 **SEVENTH AFFIRMATIVE DEFENSE**

25 Plaintiffs' claims are barred because the alleged damages, if any are proven, were
26 not proximately caused by any act or omission of any of the Defendants.
27
28

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of a responsible, superseding, and/or intervening cause.

NINTH AFFIRMATIVE DEFENSE

Defendants state that if Plaintiffs have suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident or preexisting condition, without any negligence and culpable conduct by Defendants.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission or fault of one or more persons or entities over whom Defendants exercised no control and for whom Defendants are not legally responsible, including, without limitation, Plaintiffs.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

FOURTEENTH AFFIRMATIVE DEFENSE

The product at issue in this case falls under the auspices of the Food, Drug and Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration, and therefore, Federal law preempts Plaintiffs' claims. *See*, 21 U.S.C. §301 *et. seq.* *See also*, 71 Fed. Reg. 3922 (January 24, 2006).

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants did not make to Plaintiffs nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Defendants of any alleged breach of warranty. Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future, as enacted in the State of California, and any other state whose law is deemed to apply in this case.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by comments j and k to Section 402A of the Restatement (Second) of Torts.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' product liability claims are barred because the benefits of the relevant product outweighed its risks.

1 **NINETEENTH AFFIRMATIVE DEFENSE**

2 Plaintiffs' claims are barred in whole or part because the product at issue was at all
3 times properly prepared, packaged, and distributed, and was not defective or
4 unreasonably dangerous.

5 **TWENTIETH AFFIRMATIVE DEFENSE**

6 Any imposition of punitive damages in this case against Defendants is barred to
7 the extent that the manner in which such punitive damages are calculated violates the
8 Constitution of the United States or the Constitution of the State of California.

9 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

10 Any award of punitive damages in this case against Defendants is barred to the
11 extent that the amount of such an award violates the Constitution of the United States or
12 the Constitution of the State of California.

13 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

14 Plaintiffs have failed to plead fraud with specificity.

15 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

16 Defendants are entitled to a setoff for all amounts paid, payable by or available
17 from collateral sources.

18 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

19 The Complaint fails to state a cause of action against Defendants because there is
20 no private right of action under the applicable federal law. To the extent Plaintiffs'
21 claims are based on alleged misrepresentations or omissions made to FDA, such claims
22 are barred pursuant to *Buckman v. Plaintiffs' Legal Community*, 531 U.S. 341 (2001).
23

24 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

25 Plaintiffs knowingly and voluntarily assumed any and all risks associated with the
26 use of the product at issue, barring in whole or in part the damages Plaintiffs seek to
27 recover.
28

1 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

2 In the event Defendants, or any of them, are held liable to Plaintiffs, or any of
 3 them, which liability is expressly denied, or a settlement of judgment against Defendants,
 4 or any of them, is reached, Defendants request an apportionment of fault be made as
 5 permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle*
 6 *Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of
 7 indemnification and contribution be entered against all other persons and entities in
 8 accordance with that apportionment of fault.

9 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

10 The amount of any award on behalf of Plaintiffs, or any of them, for non-
 11 economic loss must be allocated according to the provisions of California Civil Code
 12 Section 1431.2 ("Proposition 51").

13 **TWENTY- EIGHTH AFFIRMATIVE DEFENSE**

14 Defendants specifically reserve the right to amend their Answer by adding
 15 defenses, counterclaims, cross claims or by instituting third party actions as additional
 16 facts are obtained.

17 WHEREFORE, having fully answered, Defendants specifically controvert
 18 Plaintiffs' Prayer for Relief including Paragraphs (1)-(6).

19 **JURY DEMAND**

20 Defendants hereby demand a trial by jury of all the facts and issues in this case
 21 pursuant to Federal Rule of Civil Procedure 38(b).

22 Dated: June 29, 2007

23 DRINKER BIDDLE & REATH LLP

24 

25 BRENDAN N. BUONAIUTO

26 Attorneys for Defendants

27 ORTHO-MCNEIL PHARMACEUTICAL,
 28 INC. and MCKESSON CORPORATION